ON, Canada, [3]Unither Biotech Inc., Magog, QC, Canada, [4]United Therapeutics Corporation, Research Triangle Park, NC, USA

OBJECTIVES: Treprostinil is available in two forms (inhaled vs. infused) for the treatment of patients with pulmonary arterial hypertension (PAH) and New York Heart Association (NYHA) Class II-IV symptoms. The preference from 384 members of the general public for the inhaled form, and this population's willingness-to-pay (WTP) in additional monthly insurance premiums for the inclusion of this treatment on a hypothetical insurance scheme have been previously reported. The present cost-benefit analysis (CBA) explored whether it would be cost-beneficial to include inhaled treprostinil to a list of medications reimbursed by private third-party payers in Canada, for PAH NYHA Class III patients. **METHODS:** The CBA was based on a hypothetical population of 100,000. Total yearly benefits were calculated by targeting subjects 18 years of age or older and active in the workforce, applying the percentage of subjects who prefer inhaled treprostinil to infused treprostinil (85.8%) and their median monthly WTP ($CAD21.50) multiplied by 12. Potential costs were evaluated by estimating the number of potential PAH patients in the hypothetical cohort, 18 years of age or older and in NYHA Class III category, multiplied by the annual cost of using inhaled treprostinil ($117,893). The final cost-benefit to third-party payers was appraised by subtracting the potential costs from the potential benefits. **RESULTS:** Based on prevalence rates, the hypothetical starting cohort would yield 2 patients, resulting in expected costs of $235,786 to third-party payers. The estimated number of subjects willing to pay for the inclusion of inhaled treprostinil on the formulary of reimbursed drugs was 37,540, generating benefits of $9,685,320. Hence, the expected difference (benefits minus costs) was $9,449,534. **CONCLUSIONS:** The inclusion of inhaled treprostinil to formularies of reimbursed medications would be highly cost-beneficial to private third-party payers in the province of Ontario, Canada, for patients with PAH and NYHA Class III symptoms.

PRS21

COST-EFFECTIVENESS OF BUDESONIDE/FORMOTEROL VERSUS FLUTICASONE/SALMETEROL BASED ON REAL-WORLD EFFECTIVENESS IN PATIENTS WITH COPD

Hedegaard M[1], Janson C[2], Lisspers K[2], Ställberg B[2], Johansson G[2], Jörgensen L[1], Larsson K[3]
[1]AstraZeneca, Södertälje, Sweden, [2]Uppsala University, BMC, Uppsala, Sweden, [3]Karolinska Institutet, Stockholm, Sweden

OBJECTIVES: Fixed combinations of inhaled corticosteroids and long-acting β_2-agonists are widely used in treatment of patients with chronic obstructive pulmonary disease (COPD) to reduce exacerbations. Cost-effectiveness analyses comparing the costs and effects of the fixed combinations budesonide/formoterol and fluticasone/salmeterol in COPD are scarce. The objective of this study was to evaluate the cost-effectiveness of budesonide/formoterol relative to fluticasone/salmeterol based on up to eleven years of real-world effectiveness data (NCT01146392) from a Swedish health care perspective. **METHODS:** Resource use and effectiveness data were collected retrospectively from primary care medical records' data, patients ≥18 years, both sexes, with a diagnosis of COPD (J44) and merged with Swedish hospital, drug, and cause of death register data from 1 January 1999 to 31 December 2009. Propensity score matching of treatment groups was done at the index date (first prescription of fixed combination post COPD diagnosis). Exacerbations were defined as hospitalisations and emergency room visits for COPD, prescription of glucocorticosteroids and/or prescription of antibiotics for respiratory tract infections. Annual exacerbation rates were calculated using Poisson regression. The effectiveness variable was the number of exacerbations avoided. Direct costs were calculated by applying year 2010 Swedish unit costs to the annual resource use. Bootstrapping was used to quantify uncertainty around estimates. **RESULTS:** Based on 2734 patients in each treatment group, the annual exacerbation rate was 0.800 for patients treated with budesonide/formoterol and 1.090 for patients treated with fluticasone/salmeterol (26.6% reduction, $p<0.0001$). Treatment with budesonide/formoterol was found to be cost-saving compared with treatment with fluticasone/salmeterol (total average annual per patient cost of SEK12 580 [€1318] and SEK15 979 [€1675], respectively). **CONCLUSIONS:** Budesonide/formoterol was the dominant strategy (more effective at lower cost) compared to fluticasone/salmeterol for the treatment of patients with COPD based on 11 years of real-world effectiveness data.

PRS22

COST-EFFECTIVENESS OF BECLOMETHASONE/FORMOTEROL VERSUS FLUTICASONE/SALMETEROL IN THE TREATMENT OF PATIENT WITH MODERATE TO SEVERE ASTHMA IN SPAIN

Collados C[1], Ojeda P[2], Martín V[3], Rejas J[4]
[1]Universidad Carlos III de Madrid, Getafe (Madrid), Spain, [2]Clínica de Asma y Alergia Dres. Ojeda, Madrid, Spain, [3]Trial Form Support, S.L., Alcobendas, Spain, [4]Pfizer España, Alcobendas/Madrid, Spain

OBJECTIVES: To estimate the cost-effectiveness of Beclomethasone/Formoterol (BF) versus Fluticasone/Salmeterol (FS) in the treatment of adult out-patients with moderate to severe asthma from the perspective of the Society in Spain. **METHODS:** A Markov model was developed with five asthma health states: successful control, sub-optimal control, outpatient-managed exacerbation, inpatient-managed exacerbation, and death. Weekly transition probabilities were derived from the published 12-weeks ICAT SE study. Resources utilization were obtained from a published Spanish study designed *ad-hoc* to ascertain health care resources utilization, the so-called lost-workday-equivalents, and corresponding costs related with treatment of asthma in the year 2011. Time horizon was set at 12 weeks in the basecase scenario. Effectiveness was expressed as quality-adjusted life years (QALY) gain. The cost-effectiveness was expressed as an incremental cost effectiveness ratio (ICER). Bootstrapping techniques (10,000 re-samples) were used to obtain the probabilistic ICER, its 95% percentile confidence interval (CI) and the cost-effectiveness acceptability curve. Univariate and probabilistic sensitivity analysis (PSA) were also applied and included, among others, extension of the horizon to one year and the perspective of the NHS only. **RESULTS:** Compared with FS, BF was associated with a slightly increase in QALY gain; 0,7974 vs. 0,7945 while differential costs were always lower favoring BF and yielding to a mean ICER dominant (95% CI: dominant; €46,930) per QALY gained. In 96% of re-samples, the ICER was below the threshold of €30,000 per QALY, considered as cost-effective in Spain. Univariate and PSA were robust and confirmed results of the basecase scenario. **CONCLUSIONS:** From the Spanish societal and NHS perspectives in year 2011, Becomethasone/Formoterol produced similar QALY gain at a lower cost when compared with Fluticasone/Salmeterol in a highly meaningful number of replications and scenarios. Thus, Beclomethasone/Formoterol may be considered a cost-effective alternative in the treatment of moderate to severe asthma in Spain.

PRS23

PHARMACOECONOMIC ANALYSIS OF ROFLUMILAST FOR TREATMENT OF ADULT PATIENTS WITH SEVERE-TO-VERY SEVERE CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD)

Margieva A, Omelyanovsky V, Avxentyeva M, Krysanov I, Zorin N, Andreyeva N
Research Center for Clinical and Economic Evaluation and Pharmacoeconomics, Russian National Research Medical University, Moscow, Russia

OBJECTIVES: To conduct comparative pharmacoeconomic analysis of roflumilast+formoterol versus formoterol monotherapy in adult patients with severe-to-very severe COPD. **METHODS:** Analysis of the published clinical trials was conducted to evaluate comparative efficacy and safety of the studied therapy options. Expected difference in direct medical costs was calculated in Excel model based on clinical trial data about decreased number of exacerbations on roflumilast+formoterol therapy. 1-year costs of treatment were calculated from the Russian health care system point of view. Parameter uncertainty was explored using one-way sensitivity analysis. **RESULTS:** Patients on combination therapy have 20.7% less exacerbations that leads to decreased costs of treatment. The annual treatment cost per 1 patient was 37.93 USD less for roflumilast+formoterol therapy than for formoterol. The one-way sensitivity analysis showed that the results are sensitive to the variations of key model parameters: for example combination therapy remained the cheaper alternative when the price for roflumilast was no more than ± 5.0-5.2% from the basic level. **CONCLUSIONS:** The combination of roflumilast + formoterol on average was more effective and cost-saving treatment option for patients with severe-to-very severe COPD, but the results are sensitive to the variations of price of roflumilast, the length of stay costs and the duration of hospital stay for COPD exacerbations.

PRS24

COST-EFFECTIVENESS OF VARENICLINE COMPARED WITH BUPROPION AND NRT (NICORETTE) FOR SMOKING CESSATION IN AUSTRIA

Walter E, Mercsanits D
Institute for Pharmaeconomic Research, Vienna, Austria

OBJECTIVES: Austria's smoking-rate is among the world highest. Varenicline has been shown to be an effective and well-tolerated intervention for smoking cessation. The objective of this study was to evaluate and compare the cost-effectiveness of varenicline with bupropion and nicotine-replacement-therapy (NRT) for smoking cessation in Austria. **METHODS:** A markov-model was used to demonstrate the Benefits of Smoking Cessation on Outcomes (BENESCO model). The model simulates the incidence of four smoking-related morbidities: lung-cancer, chronic-obstructive-pulmonary-disease, coronary-heart-disease and stroke. The model computes costs, quality-adjusted-life-years (QALYs) and life-years (LYs) gained. Incremental cost-utility-ratios were calculated, adopting a lifetime perspective. Efficacy data were obtained from a pooled varenicline phase 3a studies (22.5% for varenicline and 15.7% for bupropion) and from Silagy(2005) for NRT (15.5%). QALYs, life-years and costs were discounted at 5% p.a. **RESULTS:** The analyses imply that for Austria, smoking cessation using varenicline versus budropion or NRT is associated with reduced smoking-related morbidity and mortality. The number of morbidities and mortalities avoided over lifetime, per 1000 smokers attempting to quit, amounts to 7.36 cases of morbidities and 4.14 deaths if varenicline is used instead of bupropion and 7.40 morbidities and 4.14 mortalities when varenicline is used in place of NRT. The number of QALYs gained over lifetime, per 1000 smokers, was 16.64 (15.32 LYs gained) in case of varenicline vs. bupropion and 16.74 QALYs gained (15.40 LYs gained) for varenicline vs. NRT. The incremental cost-utility-ratio of varenicline vs. bupropion amounts to 5,367€ and for varenicline vs. NRT it is 4,070€. Additional costs were paid out-of-pocket. Probabilistic-sensitivity-analyses demonstrated the robustness of the model regarding assumptions and input-parameters. **CONCLUSIONS:** This cost-effectiveness analysis demonstrated that varenicline treatment is cost-effective in Austria. Our results suggest that funding varenicline as a smoking cessation aid is justifiable from a health care resource allocation perspective.

PRS25

COST ANALYSIS OF OMALIZUMAB USE IN PATIENTS WITH SEVERE UNCONTROLLED ASTHMA WITHIN THE MEXICAN PUBLIC HEALTH CARE SYSTEM

Lemus-Carmona E[1], Reyes-Lopez A[2], Jimenez Aranda P[3]
[1]Novartis Pharmaceuticals Corporation, Mexico City, Mexico, [2]Mexican Children Hospital, Mexico City, Mexico, [3]Novartis, Coyoacan, Mexico

OBJECTIVES: To analyze the cost-effectiveness of Omalizumab in addition to Standard of Care (SoC) in the treatment of paediatric patients (>6 yeas-old) with severe uncontrolled asthma from the perspective of the Public Health Care System in México. **METHODS:** A Markov model, with cycle duration of 2 weeks, was designed to analyze the cost-effectiveness of Omalizumab vs SoC. Effectiveness was evaluated by the number of exacerbations avoided. The model identifies 4 health-states, and death based on symptoms and exacerbations with and without omalizumab. Transition probabilities were obtained from two clinical studies identified after a systematic review, with approximately 627 patients. Omalizumab showed a reduction of 43% in the asthma exacerbation rate vs SoC (Lanier, 2009). Model time horizon was 20 years, with treatment duration of 6 years. A discount rate of 5% was used for costs and outcomes. Direct medical costs associated with exacerbations were elicited from an expert panel of clinicians and valuated by the unitary cost list of the Mexican Institute of Social Security. Drug costs are those from public tenders 2012. (US$1=MX$13.8). Probabilistic sensitivity analysis was performed using Monte Carlo technique. **RESULTS:** The expected 20–year costs and number of exacerbations per patient with each treatment were: Omalizumab US$96,483/31.52; and SoC US$49,857/39.84. It represents 8.3 exacerbations avoided with an incremental cost-effectiveness ratio of US$5,617 per exacerbation avoided for omalizumab versus SoC, below the Mexican threshold of 1GDP *per-cápita*=US$8,586. Probabilistic sensitivity analysis showed omalizumab was below the threshold 95% of the times, according to the acceptability curve. The model is more sensitive to changes in efficacy than price. **CONCLUSIONS:** For paediatric patients with severe uncontrolled asthma, treatment with omalizumab is a cost-effective option compared with current SoC in the health system. The higher drug acquisition cost of Omalizumab is off-set by the lower rate of exacerbations seen with patients on omalizumab and their related costs.

PRS26

ECONOMIC EVALUATION OF OMALIZUMAB IN PATIENTS WITH UNCONTROLLED SEVERE ALLERGIC ASTHMA FROM THE PUBLIC PAYER PERSPECTIVE IN BRAZIL

Suzuki C[1], Pepe C[2], Silva NL[3]
[1]*Novartis, São Paulo, Brazil,* [2]*MedInsight, São Paulo, São Paulo, Brazil,* [3]*Novartis Biociências SA, Sao Paulo, Brazil*

OBJECTIVES: To assess the cost-effectiveness of adding omalizumab to standard therapy (ST) alone in patients with uncontrolled severe allergic asthma from Brazilian public health care system perspective. **METHODS:** A Markov model comparing lifetime ST with omalizumab add-on therapy was developed based on efficacy data from INNOVATE (Phase III trial, N=419, 28 weeks). Outcomes are expressed as clinically significant exacerbation (CSE) and clinically significant severe exacerbation (CSSE) avoided. A CSE is defined in INNOVATE as worsening of asthma requiring treatment with rescue systemic corticosteroids and a CSSE is defined as PEF/FEV1 <60% of personal best, in addition to requiring rescue treatment with corticosteroids or requiring emergency room treatment or hospitalization. Resources use data (physician consultations, laboratory tests, emergency rooms visits, hospitalizations, drug treatments) was obtained from INNOVATE and valued from the perspective of health care payer. In the model, subjects move back and forth between daily symptoms (optimized asthma control) and the CSE or CSSE states, as they have exacerbations and then recover. Patients can have several CSE sequentially, or can remain with no exacerbation for a long period, determined by the transition probabilities. The death states are separated into deaths from all causes and asthma-related deaths due to severe exacerbations. One-way-sensitivity-analysis (OWSA) was performed. Annual discount rate of 5% was applied both to costs and outcomes. **RESULTS:** Base case analysis showed that more CSE and CSSE were avoided with omalizumab add-on therapy than ST alone (incremental of 17.57 and 9.27 respectively) with additional cost of BRL 122,392. Hence, omalizumab ICERs are BRL 6,967/CSE avoided and BRL 13,198/CSSE avoided (1BRL=0.487USD). OWSA confirms the favorable results of base case for omalizumab. **CONCLUSIONS:** The pharmacoeconomic evaluation confirms that omalizumab add-on therapy is very cost-effective versus ST in the treatment of patients with uncontrolled severe allergic asthma (i.e. <1GDP per capita or BRL 19,000; WHO threshold).

PRS27

ONE-YEAR COST-EFFECTIVENESS OF MONTELUKAST IN 2-6-YEAR-OLD CHILDREN WITH MILD-MODERATE PERSISTENT ASTHMA IN BELARUS

Kozhanova I[1], Romanova I[1], Gavrilenko L[1], Sachek M[2]
[1]*Belarusian State Medical University (BSMU), Minsk, Belarus,* [2]*Belarusian Center for Medical Technologies, Minsk, Belarus*

OBJECTIVES: To estimate cost-effectiveness of montelukast in 2 – 6-year-old children with mild-moderate persistent asthma in Belarus. **METHODS:** A one-year decision tree model of asthma for a hypothetical cohort of 100 patients taking either montelukast (4 mg/day) or budesonide inhalation suspension (0,5mg/day) or lack of basis therapy has been constructed on the basis of the results of randomized clinical studies and local data. The number and duration of asthma exacerbations, the number of days with use of short-acting β_2-receptor agonist (salbutamol) inhaler, the number of salbutamol puffs per day have been calculated. Direct and indirect costs have been calculated (U.S. $, 2012). The cost-effectiveness ratio (CER) for montelukast, budesonide inhalation suspension or lack of basis therapy per ≪number of days without asthma attacks, exacerbations, use of short-acting β_2-receptor agonists≫ has been quantified. Sensitivity analysis has been performed. The duration and severity of asthma exacerbations, various types of pharmacotherapy were taken into consideration when sensitivity analysis was being made. **RESULTS:** In 2 – 6-year-old children with mild-moderate persistent asthma the CER of oral montedukast use was $4.1 per ≪day without asthma attacks, exacerbations, use of short-acting β_2-receptor agonists≫, CER of budesonide inhalation suspension use by nebulizer was $5.6, CER of lack of basis therapy was $6.9. The resulting trend persisted during the sensitivity analysis. **CONCLUSIONS:** In Republic of Belarus the use of oral montelukast is considered to be cost-effective in comparison to budesonide inhalation suspension or a lack of basis therapy in 2 – 6-year-old children with mild-moderate persistent asthma.

PRS28

COST-EFFECTIVENESS ANALYSIS OF MONTELUKAST IN 6-14-YEAR-OLD CHILDREN WITH MILD-MODERATE PERSISTENT ASTHMA IN BELARUS

Kozhanova I[1], Romanova I[1], Gavrilenko L[1], Sachek M[2]
[1]*Belarusian State Medical University (BSMU), Minsk, Belarus,* [2]*Belarusian Center for Medical Technologies, Minsk, Belarus*

OBJECTIVES: Global strategy for the prevention and treatment of bronchial asthma (GINA) recommends antileukotriene drugs as second-line therapy, also while treating children. The cost-effectiveness analysis (CEA) of montelukast in 6-14-year-old children suffering from mild-moderate persistent asthma has been performed to determine economic advisability of its applying in Republic of Belarus. **METHODS:** On the basis of the results of randomized studies and local data, the model of asthma process for a hypothetical cohort of 100 patients taking either montelukast (5 mg/day) or fluticasone - aerosol (250 mcg/day) has been constructed. The number and duration of asthma exacerbations, the number of days with the use of short-acting β_2-receptor agonist (salbutamol) inhaler, the number of salbutamol puffs per twenty-four hours have been chosen as important criteria influencing the process of the disease and economic burden. **RESULTS:** In children older than 6 with mild-moderate persistent asthma the priority medicine is an inhaled corticosteroid (ICS) ($CER_{fluticasone}$ – 1, 45$ per day without attacks, aggravations, use of salbutamol as compared to $CER_{montelukast}$ – 2, 62$). The trends obtained in the main analysis remain unchanged ($CEA_{fluticasone}$ – 1, 67$ for one day without attacks, aggravations, use of salbutamol as compared to $CEA_{montelukast}$ – 2, 98$) even if changes in the period of hospitalization of the patients occur (an increase up to 14.7 days) as well as in case of extension of exacerbation treatment or severity of exacerbation and additional medical aid in the emergency room for one or two days. If indirect costs caused by one of the parents' absence at work are excluded from the analysis, the priority medicine is an ICS: ($CEA_{fluticasone}$ – 1, 19$ as compared to $CEA_{montelukast}$ – 1, 95$). **CONCLUSIONS:** In the Republic of Belarus inhaled corticosteroid is the priority medicine in children older than 6 years who are able to master the technique of inhalation.

PRS29

QUEUING STATISTICAL MODEL - A NEW TOOL FOR PRELIMINARY COST-EFFECTIVENESS ASSESSMENTS

Kucharczyk P[1], Jahnz-Rozyk K[2], Kucharczyk A[2], Pancer K[3]
[1]*Military Health Institute of Medicine, Warsaw, Poland,* [2]*Military Institute of Medicine, Warsaw, Poland,* [3]*National Institute of Public Health, Warsaw, Poland*

OBJECTIVES: We hypothesized that one central laboratory would be more cost-effective than several local laboratories because price of single Chlamylege test depends on number of simultaneous tests performed. Incidence of pneumonia requiring hospitalization in Poland is app.4/1000 persons/year. For hypothetical population of one million people 4 000/ year will require hospitalization for pneumonia (VIP). We established seasonal incidence using clinical database of Military Medical Institute Warsaw. New statistical method (Queuing Model)was used. **METHODS:** Two simulation models were constructed for one million inhabitants: one, where four hospital laboratories exist, performing 10-50 tests. Second, where large central laboratory exists performing 50-200 tests. Three scenarios of morbidity were established: 1) 3000 outpatients, 1000 inpatients, equal number of patients over year; 2) 3000 outpatients, 1000 inpatients, number of patients/month related to seasonality (4 seasons specified); 3) increased influx of patients: 12000 outpatients and 4000 inpatients; number of patients/month related to seasonality. **RESULTS:** 1) in central laboratory significantly smaller number of samples were tested (mean 0.25vs0.75); 2) quarter 1 (increased patients influx) % tested in central laboratory was significantly higher but still smaller than in the local labs (0.92vs.0.95) whereas in quarter 3 (decreased patients influx) less tests performed(0.2777 vs. 0.0005); and 3) % of tests made in central lab is much higher, but still not exceeding number of tests performed in local labs (0.82vs.0.83). Central laboratory performed less tests comparing to local labs and periods of inactivity were noted which significantly increased cost of a single test. **CONCLUSIONS:** According to Queuing Model it was confirmed that creation of the central laboratory is not reasonable in terms of costs. We conclude that Queuing Statistical Model can be a useful tool for preliminary assessment ofthe cost-effectiveness of hypothesized research methodology.

PRS30

COST-EFFECTIVENESS ANALYSIS OF 100% WHEY-BASED PARTIALLY HYDROLYZED INFANT FORMULA USED FOR PREVENTION OF ATOPIC DERMATITIS IN GERMANY

Erdogan Ciftci E[1], Horodniceanu EG[2], Botteman MF[3], Detzel P[4], Verheggen BG[5]
[1]*Pharmerit International, ROTTERDAM, The Netherlands,* [2]*Pharmerit International, Bethesda, MD, USA,* [3]*Pharmerit North America, LLC., Bethesda, MD, USA,* [4]*Nestle Nutrition Institute, VEVEY, Switzerland,* [5]*Pharmerit International, Rotterdam, The Netherlands*

OBJECTIVES: Clinical evidence shows that fewer infants fed for up to 4 months with 100% partially hydrolyzed whey formula (pHF-W) subsequently develop atopic dermatitis (AD) over up to 6 years than infants fed standard formula (SF) or extensively hydrolyzed whey formula (eHF-W). The present study assessed the cost-effectiveness of pHF-W compared to SF and eHF-W for the prevention of AD in Germany. **METHODS:** A Markov cohort model was used to assess over a period of 6